chloride, and dissolve in 10 mL of 0.1 mol/L hydrochloric acid VS, 2 mL of a solution of sodium nitrate (9 in 20), 10 mL of acetic acid-ammonium acetate buffer solution (pH 4.8) and 50 mL of water. Titrate ⟨2.50⟩ with 0.1 mol/L copper (II) nitrate VS (potentiometric titration) using a copper electrode as the indicator electrode, a complex type silver-silver chloride electrode as the reference electrode, and potassium chloride solution (1 in 4) as the inner solution. Perform a blank determination in the same manner, and make any necessary correction.

Each mL of 0.1 mol/L copper (II) nitrate VS
= 21.92 mg of $C_6H_{18}N_4.2HCl$

Containers and storage Containers—Tight containers.
Storage—Light-resistant, substituted by argon gas, at 2 – 8°C.

Trientine Hydrochloride Capsules

トリエンチン塩酸塩カプセル

Trientine Hydrochloride Capsules contain not less than 90.0% and not more than 110.0% of the labeled amount of trientine hydrochloride ($C_6H_{18}N_4.2HCl$: 219.16).

Method of preparation Prepare as directed under Capsules, with Trientine Hydrochloride.

Identification Take out the contents of Trientine Hydrochloride Capsules, dry under reduced pressure not exceeding 0.67 kPa at 40°C for 4 hours, and determine the infrared absorption spectrum as directed in the paste method under Infrared Spectrophotometry ⟨2.25⟩: it exhibits absorption at the wave numbers of about 3220 cm^{-1}, 2120 cm^{-1}, 1641 cm^{-1}, 1620 cm^{-1}, 1556 cm^{-1}, 1502 cm^{-1} and 1116 cm^{-1}.

Uniformity of dosage units ⟨6.02⟩ It meets the requirement of the Mass variation test.

Dissolution ⟨6.10⟩ When the test is performed at 50 revolutions per minute according to the Paddle method using the sinker, using 900 mL of water as the dissolution medium, the dissolution rate in 15 minutes of Trientine Hydrochloride Capsules is not less than 85%.

Start the test with 1 capsule of Trientine Hydrochloride Capsules, withdraw not less than 25 mL of the medium at the specified minute after starting the test, and filter through a membrane filter with a pore size not exceeding 0.45 μm. Discard the first 10 mL of the filtrate, pipet V mL of the subsequent filtrate, add water to make exactly V' mL so that each mL contains about 0.28 mg of trientine hydrochloride ($C_6H_{18}N_4.2HCl$), and use this solution as the sample solution. Separately, weigh accurately about 28 mg of trientine hydrochloride for assay, previously dried under reduced pressure not exceeding 0.67 kPa at 40°C for 4 hours, dissolve in water to make exactly 100 mL, and use this solution as the standard solution. Pipet 10 mL each of the sample solution and standard solution separately, add exactly 5 mL of a mixture of disodium hydrogen phosphate-citric acid buffer solution (pH 8.2) and cupper (II) sulfate pentahydrate solution (1 in 20) (4:1). Determine the absorbances, A_{T1} and A_{S1} at 580 nm, and A_{T2} and A_{S2} at 410 nm, of these solutions as directed under Ultraviolet-visible Spectrophotometry ⟨2.24⟩ using a solution obtained in the same manner with 10 mL of water as the blank.

Dissolution rate (%) with respect to the labeled amount of trientine hydrochloride ($C_6H_{18}N_4.2HCl$)
$= M_s \times (A_{T1} - A_{T2})/(A_{S1} - A_{S2}) \times V'/V \times 1/C \times 900$

M_S: Amount (mg) of trientine hydrochloride for assay taken
C: Labeled amount (mg) of trientine hydrochloride ($C_6H_{18}N_4.2HCl$) in 1 capsule

Assay Take out the contents of not less than 20 Trientine Hydrochloride Capsules, weigh accurately the mass of the contents, and powder. Weigh accurately a portion of the powder, equivalent to about 0.25 g of trientine hydrochloride ($C_6H_{18}N_4.2HCl$), add 70 mL of methanol, dissolve with the aid of ultrasonic waves if necessary, and add methanol to make exactly 100 mL. Filter through a membrane filter with a pore size not exceeding 0.45 μm, discard the first 10 mL of the filtrate, and use the subsequent filtrate as the sample solution. Separately, weigh accurately about 0.25 g of trientine hydrochloride for assay, previously dried under reduced pressure not exceeding 0.67 kPa at 40°C for 4 hours, dissolve in methanol to make exactly 100 mL, and use this solution as the standard solution. Pipet 5 mL each of the sample solution and standard solution separately, add exactly 10 mL of disodium hydrogen phosphate-citric acid buffer solution (pH 8.2) and exactly 1 mL of cupper (II) sulfate pentahydrate solution (1 in 20), and shake. Determine the absorbances, A_T and A_S, at 580 nm of these solutions, obtained with the sample solution and the standard solution, as directed under Ultraviolet-visible Spectrophotometry ⟨2.24⟩, using a solution obtained in the same manner with 5 mL of methanol as a blank.

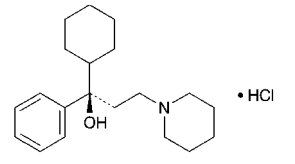
Amount (mg) of trientine hydrochloride ($C_6H_{18}N_4.2HCl$)
$= M_S \times A_T/A_S$

M_S: Amount (mg) of trientine hydrochloride for assay taken

Containers and storage Containers—Tight containers.
Storage—At 2 – 8°C.

Trihexyphenidyl Hydrochloride

トリヘキシフェニジル塩酸塩



and enantiomer

$C_{20}H_{31}NO.HCl$: 337.93
(1*RS*)-1-Cyclohexyl-1-phenyl-3-(piperidin-1-yl)propan-1-ol monohydrochloride
[*52-49-3*]

Trihexyphenidyl Hydrochloride, when dried, contains not less than 98.5% of trihexyphenidyl hydrochloride ($C_{20}H_{31}NO.HCl$).

Description Trihexyphenidyl Hydrochloride occurs as a white crystalline powder. It is odorless, and has a bitter taste.

It is soluble in ethanol (95), sparingly soluble in acetic acid (100), slightly soluble in water, very slightly soluble in acetic anhydride, and practically insoluble in diethyl ether.

Melting point: about 250°C (with decomposition).